UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOT FOR PUBLICATION

JANSSEN PRODUCTS, L.P. et al., Plaintiffs, v. LUPIN LIMITED, et al., Defendants.	Civil Action No. 10-5954-WHW-SCM **OPINION AND ORDER DENYING TEVA'S MOTION FOR LEAVE TO AMEND NON-INFRINGEMENT CONTENTIONS** **[D.E. 229]**

I. INTRODUCTION

This matter comes before the Court on the motion of Defendant Teva Pharmaceuticals USA, Inc. ("Teva") to amend its non-infringement contentions. (*See* Docket Entry ("D.E.") 229, Teva's Motion to Amend). Plaintiff United States of America (the "Government") opposes the motion. (*See* D.E. 232, the Government's Opposition). Plaintiffs Janssen Products, L.P., Janssen R&D Ireland, and G.D. Searle, LLC (collectively, "Janssen") neither consent to nor oppose Teva's motion. (*See* D.E. 231, Janssen's Response). The Court has considered all of the submissions of the parties pursuant to Fed. R. Civ. P. 78 and, for the reasons set forth below, Teva's motion is **DENIED**.

II. BACKGROUND AND PROCEDURAL HISTORY

On March 16, 2011, Janssen filed its initial complaint [D.E. 1] against Teva, asserting infringement of its U.S. Patent No. 5,843, 946 (the "'946 patent") and U.S. Patent No. 7,700,645 (the "'645 patent"). (*See* D.E. 1, Complaint). Janssen then filed an amended complaint in the now consolidated Civil Action No. 11-1509 on March 24, 2011, adding U.S. Patent No. 6,248,775 (the "'775 patent"). (*See* D.E. 6, Civil Action No. 11-1509). Pursuant to the Court's scheduling orders, Teva served its preliminary non-infringement contentions for the '946, '645, and '775 patents on Janssen on November 18, 2011. (*See* D.E. 229-1, Teva's Brief in Support, at *4). Since Teva served its preliminary contentions, Janssen asserted two more patents against Teva, U.S. Patent Nos. RE42,889 (the "'889 patent") and RE43,596 (the "'596 patent"), in Civil Action Nos. 12-3569 and 12-5358. *Id.* at *4-5. Janssen filed its complaint asserting infringement of the '889 patent on June 13, 2012, and its complaint asserting infringement of the '596 patent August 24, 2012. Since then, both of the aforementioned actions have been consolidated with the instant action by the Court. *Id.*

Teva served its non-infringement contentions for the '889 patent on August 7, 2012. (*See* D.E. 229-1, Teva's Brief in Support of Motion). Pursuant to the Court's scheduling orders,

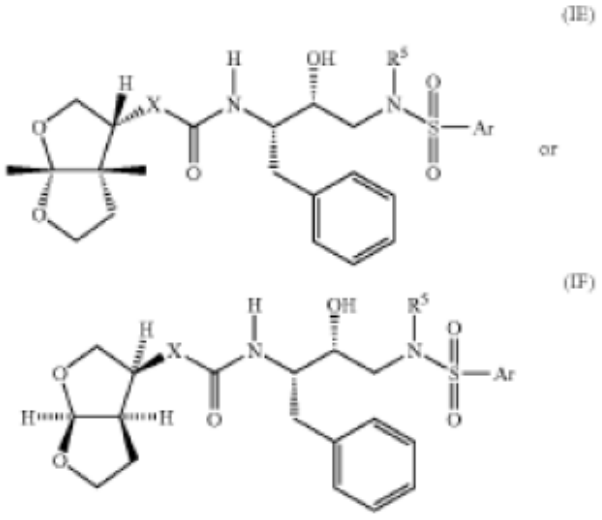
Teva served its preliminary non-infringement contentions for the '946, '645, and '775 patents on Janssen on November 18, 2011. *Id.* at *6. Teva served its non-infringement contentions for the '889 patent on August 7, 2012. *Id.* at *5. On October 5, 2012, the Court consolidated the '596 patent case was with this action, and entered a schedule for contentions and claim construction disclosures in accordance with the Local Patent Rules. *Id.*

Janssen has asserted claims 24 and 25 of the '889 patent, and claims 7-12 of the '946 patent against Teva. Teva alleges that the asserted claims of the '889 patent are similar to the asserted claims of the '946 patent, noting that claim 25 of the '889 patent and claim 7 of the '946 patent would both "cover a pharmaceutical composition comprising (i) darunavir and (ii) a pharmaceutically acceptable carrier." (*See* D.E. 229-1, Plaintiff's Brief in Support of Motion to Amend, at *6). In its non-infringement contentions for the '889 patent, Teva averred that its products do not infringe the asserted claims of the '889 patent because "Teva USA's ANDA products do not contain darunavir, but rather contain a solvate that is substantially different from darunavir." (*See* D.E. 229-1, Teva's Brief in Support of Motion, at *6). Teva now alleges that, while preparing its non-infringement contentions for the '889 patent,

it recognized a similar defense also applied to the asserted claims of the '946 patent. *Id.* Teva sent its proposed amended non-infringement contentions for the '946 patent to Janssen on October 10, 2012, and now seeks leave to amend its contentions to add this defense. *Id.*

With regard to the '506 patent, the Government asserted claims 1, 2, and 5-9 of the '506 patent against Teva on March 15, 2011. (*See* D.E. 229-1, Teva's Brief in Support, at *6). Teva served its non-infringement contentions for the '506 patent on the Government on November 18, 2011. *Id.* Claim 1 of the '506 patent and the rest of the asserted claims all contain the limitation:

> (ii) administering to the HIV-infected mammal an effective amount of a compound of the formula:



> wherein X is oxygen, R^5 is isobutyl, and Ar is substituted phenyl.

Id. at 7.

Teva argues that the Government has asserted that the genus of compounds depicted in claim 1 of the '506 patent includes darunavir, and therefore the Government has asserted that each of the asserted claims of the '506 patent includes the limitation of "administering" darunavir. *Id.* Teva asserts that it recognized during the exchange of claim construction disclosure that the Government may also dispute the construction of the term "administering," and Teva amended its list of terms requiring construction in the Joint Claim Construction and Prehearing Statement filed on May 22, 2012 to include this term. *Id.* Teva proposes that "administering should be construed according to its "plain and ordinary meaning, which is to provide externally for the purpose of delivering into the body," whereas the Government proposes that this term should be construed to mean "managing or supervising the execution or use of the claimed compound(s) of the '506 patent." *Id.*

Teva contends that under its proposed construction, administration of the ANDA products would not infringe the asserted claims of the '506 patent because the ANDA products do not contain darunavir, and Teva now seeks leave to amend its contentions to add this defense. *Id.* at 7-8. Janssen has filed a response stating that, while it does not consent to Teva's

proposed amended non-infringement contentions, it does not oppose the amendment either. (*See* D.E. 231, Janssen's Response). The Government opposes Teva's proposed amendment and has accordingly filed opposition. (*See* D.E. 232, the Government's Opposition).

III. ARGUMENTS

A. Teva's Argument

Teva contends that the Court should grant it leave to amend its non-infringement contentions, arguing that there is good cause, Teva has been sufficiently diligent in seeking leave to amend, and that the proposed amendments would not cause significant prejudice or delay. (*See* D.E. 229-1, Teva's Brief in Support of Motion). Teva asserts that it only recognized that its darunavir hydrate non-infringement defense applies to the '946 patent while preparing a nearly identical defense for its contentions on the more recently asserted '889 patent. Teva further asserts that it recognized the non-infringement defense in its proposed amended contentions for the '506 patent during the exchange of claim construction disclosures, and that Teva and the Government addressed the claim construction issue related to Teva's proposed amended '506 patent contentions in their respective opening and responsive claim construction briefs. Accordingly, Teva argues that the substance of the non-

infringement issues in its proposed amendments to its '946 and '506 patent contentions is already in this case, and that Janssen and the Government could "readily amend their infringement contentions to address Teva's amended contentions" without significant prejudice or delay.

Teva argues that it was diligent in seeking the instant motion to amend, noting that courts have "granted leave to amend contentions under circumstances similar to this case." (*See* D.E. 229-1, Teva's Brief in Support of Motion, at *8). Teva cites to *International Development, LLC v. Richmond*, 2010 WL 3946714, at *4 (D.N.J. Oct. 4, 2010), a case where the patentee, while briefing another issue, recognized that it had omitted several of its products that it asserted were covered by the patents at issue from its infringement contentions. Teva argues that the instant matter is analogous to *International Development* because Teva only recognized its darunavir hydrate argument while preparing a nearly identical defense for its contentions regarding the '889 patent. Thus, Teva argues that it should be granted leave to amend its '946 and '506 patent non-infringement contentions because it "has been sufficiently diligent in seeking leave to amend […]." (*See* D.E. 229-1, Teva's Brief in Support of Motion, at *9).

B. The Government's Argument

The Government opposes Teva's motion, arguing that Teva has not made the requisite showing of good cause, that Teva's motion is untimely, and that granting the proposed amendments would cause undue prejudice. The Government argues that Teva was not diligent in seeking to amend its non-infringement contentions, noting that Teva sent its Paragraph IV certification notice to plaintiffs on January 31, 2011, with which Teva included a document entitled "Teva Pharmaceuticals USA, Inc.'s Detailed Statement Of The Factual and Legal Bases For Its Opinion That U.S. Patent Nos….7,470,506…Are Invalid, Unenforceable, Or Not Infringed By The Manufacture, Use Or Sale Of Its Darunavir Hydrate Tablets…" (*See* D.E. 232, Government's Brief in Opposition, at *8). The Government notes that in that document Teva spent "three single-spaced pages" outlining the factual and legal bases for its assertion that Claims 1-9 of the '506 patent would not be infringed by Teva's proposed generic product. *Id.* at *8-9. The Government notes that "although the very title of the document describes Teva's products as 'Darunavir Hydrate Tablets,' Teva did not in any way suggest that the use of darunavir hydrate was a basis to assert non-infringement as to the '506 patent." *Id.* at *9. Accordingly, the Government argues that Teva's claim that it was diligent in seeking the

instant request to include the darunavir hydrate argument to its non-infringement contentions is not credible, as the Paragraph IV certification notice that Teva served in January 2011 explicitly describes Teva's products as "Darunavir Hydrate Tablets." *Id.* at *10. Additionally, the Government contends that even if Teva's darunavir hydrate argument was credible, it would still not explain Teva's delay in seeking the instant amendment. *Id.*

C. Janssen's Response

While Janssen does not oppose Teva's motion, Janssen does assert that Teva's new non-infringement position is "baseless" and "outlandish." (*See* D.E. 231, Janssen's Brief in Response, at *3-5). Janssen alleges that Teva's assertion that its products do not contain darunavir is factually incorrect, and that the fact that Teva uses a hydrate form of darunavir has no bearing on whether Teva's ANDA product infringes the asserted claims of the '889 or '946 patents. *Id.* at *4. However, Janssen notes that this consolidated action is still at its "early stages" and that discovery is ongoing, and therefore Janssen neither consents nor objects to Teva's amendment. *Id.* at *5-7.

IV. DISCUSSION

Pursuant to Local Patent Rule 3.7, leave to amend non-infringement contentions may be granted "by order of the Court upon a timely application and showing of good cause." The Local Patent Rules are "designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *TFH Publications, Inc. v. Doskocil Manufacturing, Co., Inc.*, 705 F.Supp.2d 361, 365-66 (D.N.J. 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 WL 775115, at *2 (N.D.Cal. Nov. 5, 1998)). In contrast to the liberal standard for amending pleadings, "the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the 'shifting sands' approach to claim construction." *Id.* (quoting *Atmel Corp.*, 1998 WL 775115, at *2); *see also King Pharmaceuticals, Inc. v. Sandoz, Inc.*, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). In the District of New Jersey, the Local Patent Rules emphasize the "*ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act." *Sanofi-Aventis v. Barr Labs., Inc.*, 598 F.Supp.2d 632, 637 (D.N.J. 2009) (emphasis in original).

It should be noted, however, that Rule 3.7 "is not a straightjacket into which litigants are locked from the moment

their contentions are served." *Comcast Cable Communs. Corp. v. Finisar Corp.*, 2007 WL 716131, at *2 (N.D.Cal. March 2, 2007). Instead, "a modest degree of flexibility [exists], at least near the outset" of litigation. *Id.* Accordingly, it is important to recognize that while the Local Patent Rules strive to encourage parties to establish their contentions early on, "preliminary infringement contentions are still preliminary." *TFH Publications, Inc.*, 705 F.Supp.2d at 366 (quoting *General Atomics v. Axis-Shield ASA*, 2006 WL 2329464, at *2 (N.D.Cal. Aug. 9, 2006)).

With regard to the "good cause" requirement of Rule 3.7, the Federal Circuit has stated that parties must "proceed with diligence in amending when new information comes to light in the course of discovery." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366-68 (Fed. Cir. 2006). The party seeking to amend bears the burden of establishing diligence. *Id.* at 1366; *Jazz Pharms., Inc. v. Roxane Labs.*, Inc., 2013 U.S. Dist. LEXIS 28374, at *7 (D.N.J. Feb. 28, 2013) (citing *West v. Jewelry Innovations, Inc.*, 2008 U.S. Dist. LEXIS 84928, at *1 (N.D.Cal. Oct. 8, 2008)). Moreover, a party must not only prove that it was diligent in seeking leave to amend, but also prove that it was diligent in discovering the basis for the proposed amendment. *Id.*

The Court, in its discretion, concludes that Teva did not act diligently in seeking leave to amend its non-infringement contentions, and therefore Teva has failed to make a showing of good cause pursuant to L. Pat. R. 3.7. Specifically, the Court finds that Teva has not sufficiently explained its delay in seeking to amend its non-infringement contentions to add the darunavir hydrate argument. As the Government notes, it is apparent that Teva recognized that its products contained darunavir hydrate at the time it served its Paragraph IV certification on January 31, 2012. While there is no rule that limits an ANDA filer in litigation to the defenses in its notice letter, the Court cannot ignore that Teva, by its own admission, first recognized its darunavir hydrate argument in early April of 2012, nearly six months before filing the instant motion.

Teva cites *TFH Publications, Inc.* in support of the instant motion. 705 F.Supp.2d 361. However, the Court notes that the plaintiff in *TFH* moved to amend its infringement contentions within two months of filing their initial contentions. *Id.* at 363. In the instant matter, Teva has waited nearly one year since filing its initial contentions, and nearly six months since the time Teva alleges to have become aware of its darunavir hydrate argument. Moreover, the Court notes that *TFH* did not arise under the Hatch-Waxman Act and therefore did not

require the "*ultra* early disclosure of infringement and invalidity contentions" mandated by this Court's Local Patent Rules. *See Sanofi-Aventis*, 598 F.Supp.2d at 637.

In determining whether Teva's delay in seeking the amendment is undue the Court must consider Teva's reasons for not seeking leave to amend sooner. *See King Pharmaceuticals, Inc. v. Sandoz, Inc.*, 2010 WL 2015258, at *4 (May 20, 2010). Here, Teva has not articulated any explanation for its delay in seeking leave to amend its non-infringement contentions, instead providing the conclusory assertion that "Teva has been sufficiently diligent in seeking leave to amend its non-infringement contentions." (*See* D.E. 242, Teva's Reply Brief, at *4). Teva's bare assertion of diligence does not satisfy the good cause requirement of Local Patent Rule 3.7.

Next, the Court will briefly address the issue of prejudice. In the context of Local Patent Rule 3.7, in determining whether good cause exists, the court "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." *Acer, Inc. v. Tech, Prob. Ltd.*, 2010 WL 3618687, at *3 (N.D.Cal. Sept. 10, 2010) (citing *O2 Micro*, 467, F.3d at 1355). However, the court may only consider prejudice to the non-moving party if the

moving party is able to demonstrate diligence. *Jazz Pharms., Inc. v. Roxane Labs.*, Inc., 2013 U.S. Dist. LEXIS 28374, at *13 (citing *CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 201 (N.D.Cal. 2009); *see also Apple v. Samsung*, 2012 U.S. Dist. LEXIS 83115, at *13 (N.D.Cal. Mar. 27, 2012). Here, Teva has failed to make a showing of diligence and therefore the Court need not consider prejudice to the moving party. *See Astrazeneca AB v. Dr. Reddy's Laboraties, Inc.*, 2013 WL 1145359, at *4 (D.N.J. Mar. 18, 2013) (denying motion to amend in non-Hatch-Waxman case where moving party delayed seven months in seeking amendment); *see also Apple v. Samsung*, 2012 U.S. Dist. LEXIS 83115, at *13. Accordingly, the Court finds that Teva has failed to show good cause and the motion to amend must be denied.#

V. CONCLUSION AND ORDER

The Court has considered the papers submitted pursuant to Fed. R. Civ. P. 78 and, for the reasons set forth above,

IT IS on this 9th day of May, 2013,

ORDERED that Defendant Teva's Motion for Leave to Amend Non-Infringement Contentions is **DENIED.**

Honorable Steve Mannion, U.S.M.J.
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for the District of New Jersey
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